OCT 1 9 2000

K002566

510K Summary

Regulatory Authority: Safe Medical Devices Act of 1990. CFR 807.87

Company Name:

LumaLite, Inc.
2810 Via Orange Way, Suite B
Spring Valley, CA 91978

Company Contact:

Joe Forehand
LumaLite, Inc.
2810 Via Orange Way, Suite B
Spring Valley, CA 91978
(619) 660-5410

Device Name:

Model 2100 Cure Light

Predicate Devices:

Nova Cordless Curing Light	K000393	Nova/Da Vinci Systems Inc.
Spectrum 800 Curing Light	K982318	Dentsply
Model 2000 Cure Light	K992102	LumaLite, Inc.

Device and indications for use:

The Model 2100 Cure Light provides visible light irradiation for the curing of dental VLC resin products.

Discussion:

Since the intended use and technical specifications of the LumaLite Model 2100 Cure Light are virtually identical to the predicate devices and the differences in the device only make it easier to use, more reliable and more adaptable to a variety of dental practice situations, we believe that the Luma Light 2100 Cure Light is substantially equivalent to the predicate devices and can be marketed under Section 510 (k) of the FD&C Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 9 2000

Mr. Joseph M. Forehand
LumaLite, Incorporated
2810 Via Orange Way. Suite B
Spring Valley, California 91978

Re: K002566
Trade Name: LumaLite Cure Light, Model 2100
Regulatory Class: II
Product Code: EBZ
Dated: August 16, 2000
Received: August 17, 2000

Dear Mr. Forehand:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002566

Indications Statement

510(k) Number: K002566

Device Name: Model 2100 Cure Light

Indication for Use:

The LumaLite Model 2100 Cure Light provides visible light irradiation for the curing of dental VLC resin products.

(Please do not write below this line—continue on another page if needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

Optional Format 1-2-96

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002566